UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN SLEEP-DISORDERED BREATHING TREATMENT SYSTEMS AND COMPONENTS THEREOF

Investigation No. 337-TA-890

NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST AND BONDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the final initial determination ("ID") issued by the presiding administrative law judge ("ALJ") on August 21, 2014, finding a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in this investigation.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at http://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 23, 2013, based on a complaint filed by ResMed Corporation of San Diego, California; ResMed Incorporated of San Diego, California; and ResMed Limited of New South Wales, Australia (collectively, "ResMed"). 78 *Fed. Reg.* 52564 (Aug. 23, 2013). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 32-37, 53, 79, 80, and 88 of U.S. Patent No. 7,997,267 ("the '267 patent");

claims 1-7 of U.S. Patent No. 7,614,398 ("the '398 patent"); claim 1 of U.S. Patent No. 7,938,116 ("the '116 patent"); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 (the '060 patent); claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 ("the '883 patent"); claims 1, 3, 6, 7, 9, 29, 32, 35, 40, 42, 45, 50, 51, 56, 59, 89, 92, 94, and 96 of U.S. Patent No. 7,178,527 (the '527 patent); claims 19-24, 26, 29-36, and 39-41 of U.S. Patent No. 7,950,392 (the '392 patent); and claims 13, 15, 16, 26-28, 51, 52, and 55 of U.S. Patent No 7,926,487 ("the '487 patent"). The notice of investigation named the following respondents: BMC Medical Co., Ltd. of Beijing, China; 3B Medical, Inc. of Lake Wales, Florida; and 3B Products, L.L.C., of Lake Wales, Florida (collectively "Respondents"). The Office of Unfair Import Investigations ("OUII") is participating in the investigation.

On January 9, 2014, the ALJ issued an ID granting a motion by ResMed to amend the complaint and notice of investigation to substitute U.S. Patent No. RE 44,453 ("the '453 patent") for the '398 patent and to terminate the investigation as to the '398 patent. *See* Order No. 7 (Jan. 9, 2014). The Commission determined not to review the ID. *See* Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Amend the Complaint and Notice of Investigation (Feb. 10, 2014); 79 *Fed. Reg.* 9000-01 (Feb. 14, 2014).

On February 24, 2014, the ALJ issued an ID granting a motion by ResMed to withdraw its allegations with respect to the '116 patent. *See* Order No. 11 (Feb. 24, 2014). The Commission determined not to review the ID. *See* Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Partially Terminate the Investigation by Withdrawing Allegations with Respect to U.S. Patent No. 7,938,116 (March 11, 2014).

On March 18, 2014, the ALJ granted a motion by ResMed to terminate the investigation as to claims 26-28 of the '487 Patent. *See* Order No. 20 (Mar 18, 2012). The Commission determined not to review the ID. *See* Notice of Commission Determination Not to Review an Initial Determination Granting Complainants' Unopposed Motion for Partial Termination of the Investigation by Withdrawal of Claims 26-28 of U.S. Patent No. 7,926,487 (Apr. 29, 2014).

On August 21, 2014, the ALJ issued his final ID, finding a violation of section 337 by Respondents with respect to certain asserted claims of the '392, '267, '060, '883, '527, and '453 patents. The ALJ found no violation of section 337 with respect to the asserted claims of the '487 patent. Specifically, the ALJ found that the Commission has subject matter jurisdiction, *in rem* jurisdiction over the accused products, and *in personam* jurisdiction over the respondents. ID at 10-11. The parties stipulated to importation of the accused products and the ALJ found that the importation requirement of section 337 (19 U.S.C. § 1337(a)(1)(B)) has been satisfied. *Id.* at 3. The ALJ found that the accused products infringe asserted claims 1, 9, 32, 89, and 92 of the '527 patent; asserted claims 19, 21, 29, 32, and 36 of the '392 patent; asserted claims 32-34 and 53 of the '267 patent; asserted claims 30, 37, and 38 of the '060 patent; asserted claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent; and asserted claim 2 of the '453 patent. *See* ID at 23, 46, 57-58, 71-78, 95, 99, and 102. The ALJ found that Respondents failed to establish by clear and convincing evidence that the asserted claims of the '392, '267, '060, '883, '527, or claim 2

of the '453 patents were invalid in light of the cited prior art references. *See id.* at 25-45, 48-55, 96, and 100. The ALJ concluded that the accused products satisfy each limitation of claims 4 and 7 of the '453 patent but found those claims invalid in view of the prior art. *See id.* at 103-139. The ALJ also found that the accused products satisfy each limitation of asserted claims 13, 51, 52, and 55 of the '487 patent, but found those claims invalid in view of the prior art. *See id.* at 78-92. The ALJ further found that ResMed established the existence of a domestic industry that practices the asserted patents under 19 U.S.C. § 1337(a)(2). *See* ID at 139-188.

On September 3, 2014, Respondents and the Commission investigative attorney filed petitions for review of the ID. That same day, ResMed filed a contingent petition for review of the ID. On September 11, 2014, the parties filed responses to the various petitions and contingent petition for review.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, with respect to the '487 patent, the Commission has determined to review the ALJ's construction of the claim term "gas washout vent" and construe the limitation to mean "a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere." As a result of the new claim construction, the Commission has determined to review the ALJ's findings on infringement, invalidity, and the technical prong of the domestic industry requirement. Regarding the '453 patent, the Commission has determined to review (1) the ALJ's construction of the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" and strike the ID's requirement that the claimed "retaining mechanism" must include an arrangement of moving parts; (2) the ALJ's finding that the prior art REMstar device does not anticipate the asserted claims of the '453 patent; and (3) the ALJ's findings on infringement and the technical prong of the domestic industry requirement. The Commission has also determined to review the ID's findings and conclusions regarding the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(C).

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following:

The Commission has determined to revise the ALJ's construction of the claim limitation "a retaining mechanism" recited in the asserted claims of the '453 patent and strike the requirement that it requires an arrangement of moving parts. That is, the claim limitation "a retaining mechanism configured to secure the connecting structure to the CPAP apparatus" is construed to mean "one or more parts for holding in place the CPAP apparatus that is configured to attach the connecting structure to the CPAP apparatus." *See* ID at 124. Please discuss whether the REMstar device anticipates the asserted claims under the revised construction.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the Respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants and the IA are also requested to submit proposed remedial orders for the Commission's consideration and to provide identification information for all importers of the subject articles. Complainants are also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than close of business on October 31, 2014. Reply submissions must be filed no later than the close of business on November 7, 2014. Such submissions should address the ALJ's recommended determinations on remedy and bonding. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of

Practice and Procedure (19 C.F.R. 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-890") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures,

http://www.usitc.gov/secretary/fed_reg_notices/rules/ handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton

Secretary to the Commission

Issued: October 16, 2014